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EXAMINER
WILLSE, DAVID H

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
10/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/446,629

Applicant(s)

VAGO, RAZI

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4 and 7-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 7-11 and 14 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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Claim Rejections

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4, 7, and 11 are rejected under 35 U.S.C. 101 because spacer form (claim 4, line 3) is broad enough to encompass virtually any solid occupying a volume and hence *capable* of “spacing apart” two or more (unclaimed) elements; cylinder form, sleeve form, pin form, and curved plate form (claim 4, lines 2-3) are likewise broad enough to encompass *natural* shapes of coral skeletons, which are *capable* of being implanted or inserted into a large mammal (whale, elephant, etc.) in order, for example, to evaluate tissue response (for medical research) along an unaltered, structurally intact coral surface. One definition of “machine” is “to process by or as if by machine; *especially* : to reduce or finish by or as if by turning, shaping, planing, or milling by machine-operated tools” (*Merriam-Webster’s Online Dictionary*). Coral reefs are subject to erosion, including bioerosion. For example, parrotfish bite off pieces of coral and excrete the inorganic component as silt and sand. Coral is thus *naturally* shaped and milled as if by machine. Attention is also directed to MPEP § 2113. An article of manufacture occurring in nature will not be considered patentable unless given a new form, quality, properties, or combination not present in the original article existing in nature (*Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Brogdex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex Parte Grayson*, 51 USPQ 413 (Bd. App. 1941) ). Under USPTO policy, any claim that is reasonably interpreted as covering embodiments which are statutory and embodiments which are non-statutory should be rejected. Regarding claim 11, the coral itself is viewed as an assembly of coral skeletons.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 7, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by AIMS, *CORAL GROWTH: Laser Based Underwater and Laboratory Measurements*, last updated on March 6, 1997. The species *Acropora grandis* possesses natural sizes and shapes *capable* of being implanted or inserted into a whale for medical purposes, such as studies on digestion or tissue response, and skeletal portions of said coral are *capable* of being implanted in humans, whether or not such was the intent. The naturally occurring structure meets all the limitations of claims 4, 7, and 11 for reasons explained in the above rejection under 35 U.S.C. 101.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7-11, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papacharalambous et al., "Natural coral skeleton used as onlay graft for contour augmentation of the face: A preliminary report", *Int. J. Oral Maxillofac. Surg.* 1993: 22: 260-264 (cited by the Applicant) in view of AIMS, "CORAL GROWTH: Laser Based Underwater and Laboratory Measurements", 1997 (cited by the Applicant). Papacharalambous et al. disclose that coral obtained from the genera *Acropora* possesses several advantages as a medical implant material (abstract; page 260, first paragraph; etc.) and can be shaped to serve as a bone substitute or as a

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spacer form for augmentation of a facial bone. Papacharalambous et al. are silent as to which species of *Acropora* were considered or used. *Acropora grandis* is common in the "Thailand sea" (page 260, second column, line 17) and neighboring portions of the ocean and was known to the ordinary practitioner in the art of harvesting coral (at the time of the present invention).

Since the composition, structure, and mechanical properties of *Acropora grandis* are consistent with those encompassed in the Papacharalambous et al. disclosure, substituting such a species would have led to predictable results, such as biocompatibility and osseointegration. Therefore, under the rationales suggested by the Supreme Court's decision in *KSR*, present claim 4 and others would have been obvious. Moreover, since Papacharalambous et al. consider wide availability and reduced cost to be additional advantages of using coral (page 260, first column, line 6), there would have been motivation to utilize fast growing coral species. Because the AIMS article teaches that *Acropora grandis* is a fast growing species, such would have been an obvious source for the implant material used in Papacharalambous et al. Regarding claims 8-10 and 14, official notice is taken that antibiotics and growth factors were well known in the art at the time of the present invention and would have been obvious in order to facilitate the activity of producing new bone at the site of implantation. The further limitations of claim 11 would have been obvious in order to provide a variety of implant sizes and shapes and/or to enable more extensive reconstruction procedures.

Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Response to the Applicant's Remarks

The Applicant asserts that "machined shapes are by definition not naturally occurring" (Applicant's reply of June 14, 2007: page 4, lines 10-11), but it is not clear as to what definition is being referenced by the Applicant. Attention is directed to MPEP § 2111.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday, and sometimes on Wednesday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**